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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WOOLWINE, SAMUEL C

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/623,036

Applicant(s)

STEMMER, WILLEM P.C.

Examiner

Samuel Woolwine

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Based on the priority date of 02/17/1994, the pending claims have been found to be free of the prior art.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,605,793.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-4 of the issued patent represent species which render the generic claims 1-4 of the instant application obvious.

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3. Regarding claim 1 of the instant application, a comparison to claim 1 of the issued patent reveals that, although there are minor differences in wording, the two claims describe the same process. The only true distinction between the claims is the limitation in claim 1 of the issued patent “d) repeating steps b) and c) *for at least two further cycles, wherein the resultant mixture in step (b) of a further cycle includes the mutagenized double-stranded polynucleotide from step c) of the previous cycle, and the further cycle forms a further mutagenized double-stranded polynucleotide.*” The corresponding limitation of claim 1 of the instant application “d) repeating steps (b) and (c)” is generic to the limitation in claim 1 of the issued patent. Because claim 1 of the instant application does not recite any step of removing the mutagenized double-stranded polynucleotide in step (c), said mutagenized double-stranded polynucleotide would inherently be present in step (d). Therefore, the only distinction between claim 1 of the issued patent and claim 1 of the instant application is the requirement in the method of the issued patent of “repeating steps b) and c) for at least two further cycles” (a species) while the method of claim 1 of the instant application only requires “repeating steps (b) and (c)” (a genus).

4. Because depending claims 2-4 of the instant application correspond exactly to depending claims 2-4 of the issued patent, and because claim 1 of the issued patent renders the claim 1 of the instant application obvious for the reasons discussed above, so then do claims 2-4 of the issued patent render claims 2-4, respectively, of the instant application obvious as a species anticipating a genus.

5. MPEP 2131.02 states:

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"A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. In re Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989)

6. Claims 1-5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,830,721.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-5 of the issued patent represent species which render the generic claims 1-5 of the instant application obvious.

7. Regarding claim 1 of the instant application, a comparison to claim 1 of the issued patent reveals that, although there are minor differences in wording, the two claims describe the same process. The only true distinction between the claims is the limitation in claim 1 of the issued patent "a) providing a population of double-stranded *overlapping* fragments". The corresponding limitation of claim 1 of the instant application "a) adding to the resultant population of double-stranded fragments" is generic to the limitation in claim 1 of the issued patent. Therefore, the only distinction between claim 1 of the issued patent and claim 1 of the instant application is the requirement in the method of the issued patent of using "overlapping" double-stranded fragments of a double-stranded template (a species) while the method of claim 1 of the instant application only requires using double-stranded fragments of a double-stranded template (a genus).

8. Because depending claims 2-5 of the instant application correspond exactly to depending claims 2-5 of the issued patent, and because claim 1 of the issued patent

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renders the claim 1 of the instant application obvious for the reasons discussed above, so then do claims 2-5 of the issued patent render claims 2-5, respectively, of the instant application obvious as a species anticipating a genus.

9. Claims 6-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-7 of U.S. Patent No. 5,830,721 for the reasons set forth below.

10. Regarding claim 6 of the instant application, a comparison to claim 6 of the issued patent reveals that, although there are minor differences in wording, the only true distinction between the claims is the limitation in claim 6 of the instant application wherein the expressed recombinant proteins have "biological activity". Claim 6 of the issued patent does not require that the expressed protein have biological activity. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time to which priority of the instant application is claimed to use the method taught by the issued patent to express proteins with biological activity.

11. Regarding claims 7-10, the limitations wherein the concentration of a specific double-stranded fragment in the mixture of double-stranded fragments in step (a) is less than 1% by weight of the total DNA, wherein the number of different specific double-stranded fragments in step (a) comprises at least about 100, wherein the size of the double-stranded fragments is from about 5 bp to 5 kb, wherein the size of the mutagenized double-stranded polynucleotide comprises from 50 bp to 100 kb, said limitations are repeated verbatim from claims 2-5 of the issued patent.

12. Regarding claim 11, wherein the method further comprises selecting the desired recombinant protein from the population of recombinant proteins, claim 7 of the issued patent teaches the method further comprising selecting selecting the desired recombinant protein from the population of recombinant proteins.

13. Claims 12-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-12 of U.S. Patent No. 5,830,721. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 8-12 of the issued patent represent species which render the generic claims 12-16 of the instant application obvious.

14. Regarding claim 12 of the instant application, a comparison to claim 8 of the issued patent reveals that, although there are minor differences in wording, the two claims describe the same process. The only true distinction between the claims is the limitation in claim 8 of the issued patent "*d) repeating steps b) and c) for at least two cycles, wherein the resultant mixture in step (b) of a cycle includes the chimeric double-stranded polynucleotide sequences from step c), and the further cycle forms a further chimeric double-stranded polynucleotide sequences whereby and the average length of chimeric polynucleotide sequences increases in each cycle.*" The corresponding limitation of claim 12 of the instant application "*d) repeating steps (b) and (c) as desired*" is generic to the limitation in claim 8 of the issued patent. Because claim 8 of the instant application does not recite any step of removing the chimeric double-stranded polynucleotide in step (c), said chimeric double-stranded polynucleotide would

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inherently be present in step (d). Therefore, the only distinction between claim 8 of the issued patent and claim 12 of the instant application is the requirement in the method of the issued patent of "repeating steps b) and c) for at least two further cycles" (a species) while the method of claim 12 of the instant application only requires "repeating steps (b) and (c) as desired" (a genus).

15. Because depending claims 13-16 of the instant application correspond exactly to depending claims 9-12 of the issued patent, and because claim 8 of the issued patent renders the claim 12 of the instant application obvious for the reasons discussed above, so then do claims 9-12 of the issued patent render claims 13-16, respectively, of the instant application obvious as a species anticipating a genus.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571) 272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SCW

  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

11/23/05